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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

OFFICIAL ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-2 are drawn to a compound, as classified in class 544, subclass 260.
- II. Claim 3 is drawn to a pharmaceutical composition comprising said compound, as classified in class 424, subclass 9.37.
- III. Claims 4-12* are drawn to a non-invasive method of monitoring tumor tissue concentration of an anticancer drug in real time, as classified in class 424, subclass 9.3.
- IV. Claims 13-27 are drawn to a non-invasive method of categorizing a tumor as sensitive or resistant to methotrexate in real time, as classified in class 424, subclass 9.2.
- V. Claims 28-39 are drawn to a method of treating a cancer sensitive to methotrexate in an individual, as classified in class 514, subclass 249.

*Note: It should be mentioned that although method claims 9-12 currently appear to be improperly dependent upon the compound of claim 1, for restriction purposes, method claims 9-12 are interpreted to be dependent upon the method of claim 4, as opposed to the compound of claim 1.

1. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

case, the combination as claimed does not require the particulars of the subcombination as claimed because the compound of Invention I does not require a pharmaceutically effective carrier of Invention II for patentability. The subcombination has separate utility such as an imaging composition or an anticancer composition.

Invention I is unrelated to Inventions III, IV and V as a product and various methods of using said product. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, methods as claimed in Inventions III, IV and V can utilize another product that is materially different from the product claimed in Invention I. For example, as opposed to using a compound as claimed in Invention I for treating a cancer sensitive to methotrexate, an N^δ-acyl derivative of N^α(4-amino-4-deoxypteroyl)-L-ornithine may alternatively be used for treating a cancer sensitive to methotrexate as claimed in Invention V. See e.g., U.S. Pre-Grant Patent Application Publication 2005/0032807 ([0025]).

Invention II is unrelated to Inventions III, IV and V as a product and various methods of using said product. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, methods as claimed in Inventions III, IV and V can utilize another product that is materially different from the product claimed in Invention I. For example, as

opposed to using a pharmaceutical composition comprising said compound as claimed in Invention II for treating a cancer sensitive to methotrexate, a pharmaceutical composition comprising an N^δ-acyl derivative of N^α(4-amino-4-deoxypteroyl)-L-ornithine may alternatively be used for treating a cancer sensitive to methotrexate as claimed in Invention V. See e.g., U.S. Pre-Grant Patent Application Publication 2005/0032807 ([0025]).

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden. As a result, restriction for examination purposes as indicated is proper. Applicant is therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

Conclusion to Restriction Requirement

The Examiner has required restriction between product and methods of using claims. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn methods of using that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of using claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of using claims will be withdrawn, and the rejoined methods of using

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of using claims may be maintained. Withdrawn methods of using claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the methods of using claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.


Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER